

EXHIBIT 1

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8 *Co-Lead/Liaison Counsel for Plaintiffs*

10 **IN THE UNITED STATES DISTRICT COURT**
11 **FOR THE DISTRICT OF ARIZONA**

12
13 IN RE BARD IVC FILTERS PRODUCTS
14 LIABILITY LITIGATION

No. MD-15-02641-PHX-DGC

15 **DECLARATION OF THOMAS KINNEY,**
16 **M.D. IN SUPPORT OF PLAINTIFFS'**
17 **OPPOSITION TO DEFENDANTS'**
18 **MOTION AND MEMORANDUM IN**
19 **SUPPORT OF MOTION TO**
DISQUALIFY THOMAS KINNEY, M.D.
AS AN EXPERT FOR PLAINTIFFS

20
21 I, Thomas B. Kinney, M.D. declare as follows:

22 1. I am an expert for the Plaintiffs.

23 2. On March 6, 2017, I co-authored an expert report in my capacity as practicing
24 physician and member of Society of Interventional Radiologists.

25 3. The expert report was a collaborative effort among the authors, similar to the
26 methodology employed had we been contributing to a medical article, professional society
27 guidance or practice parameters document, or presentation to the medical community, or to
28

1 professional societies and organizations, like the Society of Interventional Radiologists and the
2 American College of Radiology.

3 4. As stated in my expert report, at various times from 2005 thru 2008, I was a paid
4 consultant for Bard for telephone consultations concerning difficult retrievals with the Bard
5 filters, and instructed other physicians on how to insert the Recovery filter (RNF) and retrieve it.
6 I, along with Dr. John Kaufman, participated in animal experiments with the RNF, G2 and
7 G2X/Express filters. I also participated in one meeting in Chicago, Illinois when a group of
8 interventional radiology physicians were assembled to discuss issues with filter complications,
9 specifically fractures and migrations. None of the meetings I had with anyone at Bard involved
10 the conduct and legal liability matters that even remotely resemble those issues addressed in my
11 subject expert report. I have absolutely no recollection of ever meeting with a Bard attorney, and
12 any conversation I may have had with anyone involving a legal matter was about the medical
13 evidence involved and never about strategy, theories, or the potential fault or questionable
14 conduct of Bard. It was always about a particular patient's medical condition.

15 5. I have personal knowledge of all facts stated in this declaration, and if called to
16 testify, I could and would testify competently thereto.

17 **I. Consulting Agreements**

18 6. I signed an agreement on February 4, 2005 to act as a trainer for IVC filter
19 placement and retrieval. This agreement was not identified in Defendants' motion; however, in
20 an effort for transparency it is necessary for me to include it here. Pursuant to this agreement:

21 a. I trained physicians on IVC filter placement and retrieval.

22 7. I signed an agreement on April 27, 2005 to act as a consultant for Bard relating to
23 IVC filters and stent grafts. Pursuant to this agreement:

24 a. I was asked to evaluate various performance characteristics, including
25 retrieval for IVC filters and stent grafts.

26 8. I signed an agreement on July 8, 2005 to perform an animal study evaluating the
27 filters' retrieval performance and provide feedback to Bard. Pursuant to this agreement:
28

- a. I was asked to evaluate various performance characteristics of IVC Filters, including retrieval for IVC filters.
- b. On two occasions I was asked to lecture on my review of IVC filters with a focus on retrievable filters at Barrow Neurological Institute, located within St. Joseph's Hospital and Medical Center, 350 West Thomas Road, Phoenix, AZ 85013. After the lectures, the participating physicians were directed to the animal lab (using swine models) to insert and retrieve filters with supervision of instructors such as myself.
- c. I did not receive or have access to confidential information during this time period.

9. I signed a 12-month agreement on October 31, 2006 to provide advice and consultation regarding the use of Bard products to Bard customers who had requested additional assistance by contacting Bard Medical Services & Support (hereon after "MS&S"). Pursuant to this agreement:

- a. I, along with Dr. David W. Trost (Weill-Cornell Medicine), assisted the Bard sales force with clinical calls received to their filter line. I was responsible for the West Coast calls and Dr. David Trost for the East Coast calls. During this time period, I recall receiving about 2-3 calls per year.
- b. We were asked to document our conversations, and we were compensated for clinical assistance related to the cases.

10. I signed a 12-month agreement on in March 19, 2007 to perform an animal study evaluating the filters' retrieval performance and provide feedback to Bard. Pursuant to this agreement:

- a. I, along with Dr. John Kaufman, was asked to assist in an IVC filter animal study (swine models) performed in Mountain View, California
- b. I was tasked with evaluating various performance characteristics of the RNF, G2, G2X filters, specifically as to the ease of retrieval.

- c. We also evaluated angioplasty balloons during this study.
- d. Dr. Kaufman, and perhaps Dr. Venbrux, designed the protocol and experimental conditions of the study.
- e. I had no input in the design of the filters, the design of the experiments, or the analysis of the outcome data.

11. I signed a 12-month agreement on August 8, 2007 to provide research services to Bard related the G3 Feasibility Chronic Animal Study Protocol. Pursuant to this agreement:

- a. I, along with Dr. John Kaufman, was asked to assist in an IVC filter animal study (swine models) performed in Mountain View, California
- b. I was tasked with evaluating various performance characteristics of the G3 filter, specifically inserting and retrieval. The study was approximately 20 weeks long (5 months).
- c. I had no input in the design of the filters, the design of the experiments, or the analysis of the outcome data.

II. Expert Medical Review

12. Bard mischaracterizes my involvement in *Mattes v. C. R. Bard, Inc., et al.*:
- a. I did not draft a F.R.C.P. Rule 26 Expert Report.
 - b. I did not receive confidential information or internal company documents from Bard.
 - c. I did not receive attorney work product from Bard related to this case.
 - d. I did not discuss with Bard theories of liability for the case.
 - e. I did not discuss with Bard strategies for the case.
 - f. I did not discuss with Bard theories for damages for the case.
 - g. No attorney for Bard shared their legal ideas or impressions with me about the case.
 - h. In June 2006, I did provide Bard with a medical review of the injuries experienced by the patient in the *Scott Mattes vs C.R. Bard* case.

1 i. I did review the anatomy and found that nerves lying on the anterior surface of
2 the psoas muscle could result in referred pain to the right groin. I also found
3 case reports of femoral punctures resulting in femoral nerve neuropathies as
4 well. The patient had an unsuccessful retrieval attempt at the local hospital
5 where the filter was inserted. Bard flew Dr. Anthony Venbrux out to the local
6 hospital and he was successful in retrieving the filter. The patient developed a
7 post-traumatic stress response from the experience with episodes of severe
8 anxiety upon entering his prior work area in radiology.

9 j. The medical review was based upon the information known to me in June
10 2006. Bard had not shared with me their internal perforation rates or
11 information related to the increased rates they observed of perforations.

12 k. Now that I have seen the comparison data between Bard and its competitors
13 (which were provided to me for the first time by Plaintiffs' counsel in this
14 matter) and gained insight through over nine (9) years of experience since the
15 *Mattes* review occurred, I know the frequency of vena cava perforations by
16 IVC filters is not widely reported, and when reported, I know the rate of
17 perforation for reported cases has significantly increased.

18 l. I did receive a check for \$3,400.00 on July 17, 2006 for providing Bard with a
19 medical review for *Mattes v. C. R. Bard, Inc., et al.*

20 m. In my possession I have a copy of the medical review I authored which
21 supports my statements listed within this paragraph. In an abundance of
22 caution, I have not attached this review; however, it is available to the Court
23 for *in camera* review.
24

25 13. Bard mischaracterizes my involvement in *Jordan Ennis v. Hospital of the*
26 *University of Pennsylvania, et al.*:

27 a. I did not draft a F.R.C.P. Rule 26 Expert Report.

28 b. I did not receive confidential information or documents from Bard.

- c. I did not receive attorney work product from Bard related to this case.
- d. I did not discuss with Bard theories of liability for the case.
- e. I did not discuss with Bard strategies for the case.
- f. I did not discuss with Bard theories for damages for the case.
- g. I did review medical records related to the plaintiff. I estimate I spent 1 hour reviewing the records in this case.
- h. No attorney for Bard shared their legal ideas or impressions with me about the case
- i. I did receive a check for \$400.00 on February 14, 2006 for providing Bard with a medical review for *Jordan Ennis v. Hospital of the University of Pennsylvania, et al.*

III. August 2006 Meeting

14. In August of 2006, I met with John McDermott and Janet Hudnall for a few hours in the morning. At this meeting, general questions related to IVC filter fractures were raised.

15. Non-specific questions were asked of me about whether fractures fragments could cause issues. I explained that a fracture fragment staying in place near the cava might be considered analogous to a retained surgical staple; a fracture fragment that embolized could cause serious complications.

16. The other issue we discussed at this meeting was related to the altered functioning of such a filter. Loss of arms or legs could lead to less effective filtering and may result in greater mechanical loading on the remaining filter arms/legs, and may also lead to fractures.

17. This meeting did not involve discussions about any legal matter or pending litigation.

18. Bard did not share statistics with me about the rate of fractures.

19. Bard did not share internal documents with me about fracture rates.

20. I was not asked to work on or offer advice for a Remedial Action Plan, exhibit H to Bard's motion or any other internal Bard document or process to my knowledge.

1 21. I was not aware that my name appeared in the Remedial Action Plan (exhibit H),
2 and I was not provided with a copy of it. This is the first time I have seen the data and
3 documents related to the Remedial Action Plan.

4 **IV. Summary**

5 22. I have had no contact with Bard Peripheral Vascular in over nine (9) years.

6 23. I have never been given access to any of the research data or documents,
7 including the data to for the 510(k) submission for any of the Bard Filters.

8 24. I was unaware of the migration that occurred with the 33rd patient in Dr. Murray
9 Asch's study.

10 25. I was unaware of the statistical analysis conducted by Bard that showed the
11 statistically significant higher fractures and other filter related complications.

12 26. I was never tasked with requests for design review of Bard filters, nor was I
13 requested to provide input in the design of the animal experiments that we conducted for the
14 Bard Team.

15 27. I was never tasked with the design or development of Bard filters, nor was my
16 input ever sought.

17 28. During the two and a half years (2.5) that I consulted for Bard, I primarily
18 inserted and retrieved IVC filters on swine models, either to provide a demonstrative for fellow
19 physicians or in my service as a participant in the two animal studies outlined above. In addition,
20 I received 2-3 calls from physicians with questions regarding difficult retrievals. I also completed
21 two medical record reviews for individual patients.

22 29. As an expert for the Plaintiffs, I have offered opinions from my perspective as a
23 practicing physician and as a member of the Society of Interventional Radiologists. My opinions
24 are based upon documents, data, information and facts that I received for the first time while
25 retained as an expert in the above captioned matter. None of the data or information was ever
26 discussed with any attorney or employee or third party during the period of time I was consulting
27 with Bard on a number of other matters.
28

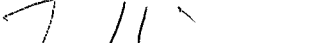
31. The bases and substance of my opinions are not based on any information I derived or received when I was a consultant for Bard.

32. The expert report that I co-authored for the PLC includes a list of all the documents, data, information and facts I considered in forming my opinions, none of which I reviewed when I was a consultant for Bard. In fact, I was not aware of the existence of any of this material or its content.

33. I was not provided with any of the data or documents that I reviewed and relied upon for my expert medical review in the above captioned matter nor asked to review or comment on any of the data or documents that I have since reviewed and relied upon in the expert report I have co-authored in this matter. This is the first time I reviewed this data and information.

34. My expertise as an engineer or designer of medical devices was never utilized by C.R. Bard. Rather, Bard sought only my clinical experience in the general area of IVC filters.

In accordance with 28 U.S. Code § 1746, I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct and that this declaration was executed on May 10, 2017.

Signature: 

Printed name: THOMAS B. KINNEY, M.D.

Address: 200 W ARBOR DRIVE, SAN DIEGO, CA 92103

Phone Number: (619) 543-3405

EXHIBIT 3

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO**

Civil Action No. 05-cv-01960-MSK-CBS

SCOTT MATTES,

Plaintiff,

v.

C.R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC.,

Defendants.

STIPULATED NOTICE OF DISMISSAL

Plaintiff, Scott Mattes, and Defendants, C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., through undersigned counsel, hereby execute this *Stipulated Notice of Dismissal*, stating as follows:

1. Pursuant to Fed.R.Civ. P. 41(a)(1), the parties dismiss this action, with prejudice, and with each party responsible for its own attorney fees and costs.

DATED this 4th day of August, 2006.

Counsel for Plaintiff Scott Mattes

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Bard Peripheral Vascular, Inc.**

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EXHIBIT 4

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

JORDAN ENNIS	:	CIVIL ACTION
	:	
v.	:	
	:	
HOSPITAL OF THE UNIVERSITY	:	
OF PENNSYLVANIA	:	NO. 06-5541

O R D E R

AND NOW, TO WIT: this 23rd day of April, 2007, it having been reported that the issues between the parties in the above action have been settled and upon Order of the Court pursuant to the provisions of Rule 41.1(b) of the Local Rules of Civil Procedure of this Court, it is

ORDERED that the above action is DISMISSED with prejudice, pursuant to agreement of counsel without costs.

MICHAEL E. KUNZ, Clerk of Court

BY: s/Charles J. Ervin
Charles J. Ervin, Deputy Clerk